

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

| | | |
|--|---|------------------------|
| SANTARUS, INC., a Delaware corporation, |) | |
| and THE CURATORS OF THE |) | |
| UNIVERSITY OF MISSOURI, a public |) | |
| corporation and body politic of the State of |) | |
| Missouri, |) | |
| Plaintiffs, |) | |
| |) | |
| v. |) | C.A. No. 07-827-GMS |
| |) | (now consolidated with |
| |) | C.A. No. 07-551-GMS) |
| PAR PHARMACEUTICAL, INC., a Delaware |) | |
| corporation, |) | |
| |) | |
| Defendant. |) | |

REPLY TO COUNTERCLAIMS

Santarus, Inc. (“Santarus”) and The Curators of the University of Missouri (the “University”) (collectively “Plaintiffs”) hereby reply as follows to the Amended Answer and Counterclaims asserted by Defendant Par Pharmaceutical, Inc. (“Defendant”):

THE PARTIES

1. Plaintiffs admit, on information and belief, the allegations of Paragraph 1 of the Counterclaims.
2. Plaintiffs admit the allegations of Paragraph 2 of the Counterclaims.
3. Plaintiffs admit the allegations of Paragraph 3 of the Counterclaims.

JURISDICTION

4. Plaintiffs admit that Par purports to bring this action under Title 35, United States Code and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, and 2202. Plaintiffs deny the remaining allegations of Paragraph 4.
5. Plaintiffs do not contest that this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202 over the Counterclaims related to U.S. Patent

Nos. 6,699,885 (“the ‘885 patent”); 6,489,346 (“the ‘346 patent”); 6,645,988 (“the ‘988 patent”); and 6,780,882 (“the ‘882 patent”). Plaintiffs deny that this Court has subject matter jurisdiction over Defendant’s counterclaims relating to U.S. Patent No. 5,840,737 (“the ‘737 patent”).

Additionally, these counterclaims are barred by the Eleventh Amendment to the United States Constitution. Plaintiffs deny the remainder of the allegations in Paragraph 5 of the Counterclaims.

6. Plaintiffs do not contest personal jurisdiction in Delaware for the purposes of this action.

FACTUAL BACKGROUND

7. Plaintiffs admit the allegations in Paragraph 7 of the Counterclaims.

8. Plaintiffs admit the allegations of Paragraph 8 of the Counterclaims.

9. Plaintiffs admit the allegations of Paragraph 9 of the Counterclaims.

10. Plaintiffs admit the allegations of Paragraph 10 of the Counterclaims.

11. Plaintiffs admit the allegations of Paragraph 11 of the Counterclaims.

12. Plaintiffs admit that the ‘737 patent, ‘988 patent, ‘346 patent, ‘885 patent, and the ‘882 patent are assigned to The Curators of the University of Missouri. Plaintiffs deny the remaining allegations in Paragraph 12 of the Counterclaims.

13. Plaintiffs admit that the Provisional Application No. 60/009,608 was filed on January 4, 1996 and is the earliest application referenced in the Related U.S. Application Data of the ‘737 patent, ‘988 patent, ‘346 patent, ‘885 patent, and the ‘882 patent. Plaintiffs deny the remaining allegations in Paragraph 13 of the Counterclaims.

14. Plaintiffs admit that the ‘737 patent, ‘988 patent, ‘346 patent, ‘885 patent, and the ‘882 patent are licensed to Santarus and relate to various combinations of omeprazole

and sodium bicarbonate, among other combinations. Plaintiffs deny the remaining allegations in Paragraph 14 of the Counterclaims.

15. Plaintiffs admit, on information and belief, the allegations of Paragraph 15 of the Counterclaims.

16. Plaintiffs deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 16 of the Counterclaims and therefore deny those allegations.

FIRST COUNT

17. Plaintiffs incorporate by reference their responses to Paragraphs 1 through 16 of the Counterclaims as if fully set forth herein.

18. Plaintiffs admit that they have asserted the '885, '346, '988, and '882 patents against Par, and that the claims of these patents cover Par's Proposed Products. Plaintiffs deny the remaining allegations in Paragraph 18 of the Counterclaims.

19. Plaintiffs deny the allegations in Paragraph 19 of the Counterclaims.

20. Plaintiffs do not contest that the Court has declaratory judgment jurisdiction over the '885, '346, '988, and '882 patents on the issue of infringement. Plaintiffs deny that this Court has subject matter jurisdiction over Defendant's counterclaims relating to the '737 patent. Additionally, these counterclaims are barred by the Eleventh Amendment to the United States Constitution. Plaintiffs deny the remaining allegations in Paragraph 20 of the Counterclaims.

21. Plaintiffs deny the allegations in Paragraph 21 of the Counterclaims.

SECOND COUNT

22. Plaintiffs incorporate by reference their responses to Paragraphs 1 through 21 of the Counterclaims as if fully set forth herein.

23. Plaintiffs deny the allegations in Paragraph 23 of the Counterclaims.

24. Plaintiffs admit that the Patents-in-Suit are valid. Plaintiffs deny the remaining allegations in Paragraph 24 of the Counterclaims.

25. Plaintiffs do not contest that the Court has declaratory judgment jurisdiction over the '885, '346, '988, and '882 patents on the issue of validity. Plaintiffs deny that this Court has subject matter jurisdiction over Defendant's counterclaims relating to the '737 patent. Additionally, these counterclaims are barred by the Eleventh Amendment to the United States Constitution. Plaintiffs deny the remaining allegations in Paragraph 25 of the Counterclaims.

26. Plaintiffs deny the allegations of Paragraph 26 of the Counterclaims.

THIRD COUNT

27. Plaintiffs incorporate by reference their responses to Paragraphs 1 through 26 of the Counterclaims as if fully set forth herein.

28. Plaintiffs deny the allegations of Paragraph 28 of the Counterclaims.

29. Plaintiffs deny the allegations of Paragraph 29 of the Counterclaims.

30. Plaintiffs deny the allegations of Paragraph 30 of the Counterclaims.

31. Plaintiffs admit that the application for U.S. Serial No. 09/481,207 was filed on January 11, 2000. Plaintiffs deny the remaining allegations in Paragraph 31 of the Counterclaims.

32. Plaintiffs deny the allegations of Paragraph 32 of the Counterclaims.

33. Plaintiffs deny the allegations of Paragraph 33 of the Counterclaims.

34. Plaintiffs deny the allegations of Paragraph 34 of the Counterclaims.

35. Plaintiffs deny the allegations of Paragraph 35 of the Counterclaims.

36. Plaintiffs admit that in a Supplemental IDS dated December 20, 2001, from the file history of the '346 patent, applicant references a poster presentation by Jeffrey O. Phillips in January 1994 at the Society for Critical Care Medicine Annual Meeting. Plaintiffs deny the remaining allegations in Paragraph 36 of the Counterclaims.

37. Plaintiffs admit that the file history for the '376 application does not specifically reference the poster presentation referenced in Paragraph 36 of the Counterclaims. Plaintiffs deny the remainder of the allegations in Paragraph 37 of the Counterclaims.

38. Plaintiffs deny the allegations of Paragraph 38 of the Counterclaims.

39. Plaintiffs admit that the Supplemental IDS states that the poster presentation referenced in Paragraph 36 of the Counterclaims related to SOS.

40. Plaintiffs admit the allegations of Paragraph 40 of the Counterclaims to the extent it refers to the Remarks section of the Supplemental IDS.

41. Plaintiffs deny the allegations of Paragraph 41 of the Counterclaims.

42. Plaintiffs deny the allegations of Paragraph 42 of the Counterclaims.

43. Plaintiffs deny the allegations of Paragraph 43 of the Counterclaims.

44. Plaintiffs admit the allegations of Paragraph 44 of the Counterclaims.

45. Plaintiffs deny the allegations of Paragraph 45 of the Counterclaims.

46. Plaintiffs deny the allegations of Paragraph 46 of the Counterclaims.

47. Plaintiffs admit the allegations of Paragraph 47 of the Counterclaims.

48. Plaintiffs admit that the prosecution history for the '376 application does not specifically reference the UMSS Presentation. Plaintiffs deny the remainder of the allegations of Paragraph 48 of the Counterclaims.

49. Plaintiffs deny the allegations of Paragraph 49 of the Counterclaims.

50. Plaintiffs admit the allegations of Paragraph 50 of the Counterclaims.

51. Plaintiffs deny the allegations of Paragraph 51 of the Counterclaims.

52. Plaintiffs deny the allegations of Paragraph 52 of the Counterclaims.

53. Plaintiffs deny the allegations of Paragraph 53 of the Counterclaims.

54. Plaintiffs admit that provisional application No. 60/009,608 is the earliest application listed in the Related U.S. Application Data of the '885, '346, '988, and '882 patents. Plaintiffs deny the remaining allegations of Paragraph 54 of the Counterclaims.

55. Plaintiffs deny the allegations of Paragraph 55 of the Counterclaims.

56. Plaintiffs deny the allegations of Paragraph 56 of the Counterclaims.

57. Plaintiffs deny the allegations of Paragraph 57 of the Counterclaims.

58. Plaintiffs admit the allegations of Paragraph 58 of the Counterclaims.

59. Plaintiffs admit the discussions referenced in Paragraph 58 of the Counterclaim occurred more than one year prior to the date the applicant filed the Provisional Application on January 4, 1996. Plaintiffs deny the remaining allegations of Paragraph 59 of the Counterclaims.

60. Plaintiffs admit that the prosecution history for the '376 application does not specifically reference the discussions referenced in Paragraph 58 of the Counterclaims. Plaintiffs deny the remaining allegations of Paragraph 60 of the Counterclaims.

61. Plaintiffs admit that the Supplemental IDS states that: "[s]uch discussions do not constitute a public use of SOS as Dr. Phillips believed that such discussions were confidential, and they were for experimental purposes only." Plaintiffs deny the remaining allegations of Paragraph 61 of the Counterclaims.

62. Plaintiffs deny the allegations of Paragraph 62 of the Counterclaims.

63. Plaintiffs deny the allegations of Paragraph 63 of the Counterclaims.

64. Plaintiffs deny the allegations of Paragraph 64 of the Counterclaims.

65. Plaintiffs admit the allegations of Paragraph 65 of the Counterclaims.

66. Plaintiffs admit the allegations of Paragraph 66 of the Counterclaims.

67. Plaintiffs admit the allegations of Paragraph 67 of the Counterclaims.

68. Plaintiffs admit the allegations of Paragraph 68 of the Counterclaims.

69. Plaintiffs admit the allegations of Paragraph 69 of the Counterclaims.

70. Plaintiffs admit the allegations of Paragraph 70 of the Counterclaims.

71. Plaintiffs deny the allegations of Paragraph 71 of the Counterclaims.

72. Plaintiffs deny the allegations of Paragraph 72 of the Counterclaims.

73. Plaintiffs deny the allegations of Paragraph 73 of the Counterclaims.

74. Plaintiffs deny the allegations of Paragraph 74 of the Counterclaims.

75. Plaintiffs deny the allegations of Paragraph 75 of the Counterclaims.

76. Plaintiffs deny the allegations of Paragraph 76 of the Counterclaims.

77. Plaintiffs deny the allegations of Paragraph 77 of the Counterclaims.

78. Plaintiffs admit that the prosecution history of the '346 patent contains a terminal disclaimer that references the '737 patent. Plaintiffs deny the remaining allegations of Paragraph 78 of the Counterclaims.

79. Plaintiffs deny the allegations of Paragraph 79 of the Counterclaims.

80. Plaintiffs admit that the prosecution history of the '885 patent contains a terminal disclaimer that references the '737 patent and the '346 patent. Plaintiffs deny the remaining allegations of Paragraph 80 of the Counterclaims.

81. Plaintiffs deny the allegations of Paragraph 81 of the Counterclaims.

82. Plaintiffs admit that the prosecution history of the '882 patent contains a terminal disclaimer that references the '737, '346, '988 and '885 patents. Plaintiffs deny the remaining allegations of Paragraph 82 of the Counterclaims.

83. Plaintiffs deny the allegations of Paragraph 83 of the Counterclaims.

84. Plaintiffs admit that the prosecution history of the '988 patent contains a terminal disclaimer that references any patent issuing from the '207 application. Plaintiffs deny the remaining allegations of Paragraph 84 of the Counterclaims.

85. Plaintiffs deny the allegations of Paragraph 85 of the Counterclaims.

86. Plaintiffs deny the allegations of Paragraph 86 of the Counterclaims.

87. Plaintiffs deny the allegations of Paragraph 87 of the Counterclaims.

88. Plaintiffs deny the allegations of Paragraph 88 of the Counterclaims.

89. Plaintiffs deny the allegations of Paragraph 89 of the Counterclaims.

90. Plaintiffs deny the allegations of Paragraph 90 of the Counterclaims.

91. Plaintiffs deny the allegations of Paragraph 91 of the Counterclaims.

92. Plaintiffs do not contest that the Court has declaratory judgment jurisdiction over the issue of enforceability related to the '885, '346, '988, and '882 patents. Plaintiffs deny that this Court has subject matter jurisdiction over Defendant's counterclaims relating to the '737 patent. Additionally, these counterclaims are barred by the Eleventh Amendment to the United States Constitution. Plaintiffs deny the remainder of the allegations of Paragraph 92 of the Counterclaims.

93. Plaintiffs deny the allegations of Paragraph 93 of the Counterclaims.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as sought in their Complaint and denying Defendant any relief on its Counterclaims.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ James W. Parrett, Jr.

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1639198

*Attorneys for plaintiffs Santarus, Inc. and
The Curators of the University of Missouri*

CERTIFICATE OF SERVICE

I hereby certify that on February 22, 2008, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

Frederick L. Cottrell, III, Esquire
Steven J. Fineman, Esquire
RICHARDS, LAYTON & FINGER, P.A.

I further certify that I caused to be served copies of the foregoing document on February 22, 2008 upon the following in the manner indicated:

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